REMARKS

Status of claims

Claims 16 and 24 are canceled herein. Claims 25-41 are added herein. Claims 1, 3, 12, 15, 18, and 22 have been amended. Claims 1-15, 18, 23, and 25-41 are pending. Claims 1-16, 18 and 22-24 were rejected.

Claims 1 and 15 have been amended in an attempt to overcome the lack of clarity observed by the Examiner. It is believed that these claims now clearly define applicants' invention.

Claim 3 has been amended to be dependent on claim 1 rather than on claim 2.

Claims 12 and 18 have been amended to make them consistent with amended claims 1 and 15, respectively.

Claim 15 has also been amended to remove one period from the end of the claim.

Claim 22 has been amended to make it dependent on claim 39. The limitations of this claim have been added to claim 15, on which it was previously dependent.

Newly added claim 25 corresponds to claim 1 with the limitations of both claim 2 and claim 3 added. Claims 26-35 are dependent on claim 25.

Newly added claim 36 corresponds to claim 15 with the limitations of claims 2 and 3 added. Claim 37 is dependent on claim 36.

Newly added claim 38 is independent. It avoids the use of the term "powder" and the term "susceptible." It is directed to a "dry" formulation in which "the anti-infective agent would destroy the viability of the organism in the dry formulation in less than three months in the absence of the protective barrier." Claims 22 and 39-40 are dependent on claim 38.

Claim rejection - 35 U.S.C. § 112, first paragraph

Claims 1, 4-16, 18 and 22-24 were rejected under 35 U.S.C. §112, first paragraph. The Examiner argues that the specification, while being enabling for the specific microorganisms listed in claim 3 and the specific anti-infective agents listed in claim 2, does not reasonably provide enablement for any and all anti-infective agents and any and all microorganisms susceptible to the anti-infective agent. This rejection is respectfully traversed.

The invention defined in the rejected independent claims, 1 and 15, involves forming a barrier between "an anti-infective agent *selected from the group consisting of betalactams, fluoroquinolones, macrolides and betalactamase inhibitors*" and "a microorganism susceptible to said anti-infective agent, *wherein the microorganism is useful in preventing or minimizing adverse effects of said anti-infective agent.*" It is thus not, as suggested by the Examiner, directed to *any* anti-infective and *any* microorganism.

The Examiner has given no reason to disbelieve the teachings of the specification that the invention is of general applicability: "The organism can be any which prevents or minimises adverse reactions of anti-infective agents when taken at same time." The initial burden of showing non-enablement rests with the Office. Applicant respectfully submits that the Office has provided no evidence of undue experimentation and thus the Office has failed to make a *prima facie* case of non-enablement. See *In re Marzocchi*, 169 USPQ 367, 370 (CCPA 1971).

New independent claims 25 and 36 include the subject matter of both claims 2 and 3. Since the Examiner admits that the specification provides enablement for the specific agents and microorganisms of claims 2 and 3, it is believed that these claims are not subject to this rejection.

New independent claim 38 calls for "(a) an anti-infective agent capable of causing adverse effects caused by destruction of commensals, (b) a microorganism useful in preventing or minimizing the adverse effects of said anti-infective agent." It thus also limits the anti-infective and the microorganism to those which would be expected to be operative with the present invention.

The Examiner also argues that the term "susceptible" is vague and indefinite. Applicants respectfully disagree. An applicant can define the claims in whatever terms they choose so long as the terms are not used in ways that are contrary to accepted meanings in the art. *In re Swinehart*, 439 F.2d 210 (CCPA 1971). A claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought. *Id.* During patent examination, the pending claims must be given their broadest reasonable interpretation consistent with the specification. *In re Prater*, 415 F.2d 1393 (CCPA 1969). The Examiner's attention, therefore, is directed to the written description where it is clear that "susceptible" means having threatened viability.

Therefore, Applicants respectfully request that the rejection of claims 1, 4-16, 18 and 22-24, under 35 U.S.C. §112, first paragraph, be withdrawn.

Claim rejection - 35 U.S.C. § 112, second paragraph

Claims 1-16, 18 and 22-24 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Claims 16, 22 and 24 have been canceled. With regard to the other pending claims the Examiner argued, generally, that the claims were confusing. The claims have been amended for clarity.

The Examiner's concerns regarding use of the term "susceptible" are addressed above.

The Examiner's concern about using the term "powder" to include a formulation containing both coated granules and more finely divided powder is believed to be misplaced. The quotation from Remington says that "this term generally refers to those *pharmaceutical dosage forms* that are made up of more or less finely divided, dry, solid material." It is not limited to a single ingredient, nor is it limited to a dosage form having particles of uniform size. Therefore, since this usage of the term "powder" is unambiguous and is consistent with the description of this embodiment in the specification, it is believed that applicant is entitled to use it in the claims.

The Examiner argues that "coating" is not clear in claim 15. Claim 15 has been amended to clarify that the anti-infective agent and the microorganism are physically separated in the tablet by the coating. The claim has also been amended to clarify that the coating protects the microorganism(s) from the anti-infective agent(s).

Claim rejection - 35 U.S.C. § 102(b)

Claims 1, 3, 6-8, 15, 16, 18 and 22-24 are rejected under 35 U.S.C. §102(b) as being anticipated by FR 6855. Applicant traverses the rejection.

Independent claims 1 and 15 have been amended to claim only formulations wherein the anti-infective agent is selected from the group consisting of "betalactams, fluoroquinolones, macrolides and betalactamase inhibitors."

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628 (Fed. Cir. 1987); MPEP 2131. Since FR 6855 does not disclose, teach or suggest formulations comprising these anti-infective agents, independent claims 1 and 15 are clearly patentable over FR 6855. Therefore, it is respectfully

submitted that claims 1-15 are patentable over FR 6855, and Applicants request withdrawal of the rejection of amended claims 1 and 15 under 35 U.S.C. §102(b).

Claims 3 and 6-8, and claims 18, 22 and 24 depend from independent claims 1 and 15, respectively, and therefore include all of the subject matter of claims 1 and 15. Therefore, it is respectfully requested that the rejection of claims 6-8 and 18, 22 and 24 under 35 U.S.C. §102(b) be withdrawn.

Claim 1 is also rejected under 35 U.S.C. §102(b) as being anticipated by FR 5247. Applicant traverses the rejection.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628 (Fed. Cir. 1987); MPEP 2131. Since FR 5247 does not disclose, teach or suggest formulations comprising the claimed anti-infective agents, independent claim 1 is clearly patentable over FR 5247. Therefore, it is respectfully submitted that claim 1 is patentable over FR 5247, and Applicants request withdrawal of the rejection of amended claim 1 under 35 U.S.C. §102(b).

Claim rejection - 35 U.S.C. § 103(a)

Claims 1-16, 18 and 22-24 were rejected under 35 U.S.C. §103(a) as being unpatentable over FR 5247 in view of FR 6855 and in further view of Black et al. Applicant traverses the rejection.

To establish a *prima facie* case of obviousness the prior art references when combined must teach or suggest all of the claim limitations. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Here, it is clear that the references cited by the Examiner do not teach or suggest all of the claim limitations.

Independent claims 1 and 15 have been amended to claim only formulations wherein the anti-infective agent is selected from the group consisting of betalactams, fluoroquinolones, macrolides and betalactamase inhibitors and the microorganism is susceptible to the anti-infective agent. Neither FR 5247, FR 6855 or Black et al., alone or in combination, teach, disclose or suggest formulations comprising the claimed anti-infective agents and microorganisms.

Black stands for no more than the admitted prior art, namely that it is desirable to administer microorganisms to overcome the adverse effects of ampicillin. The French references suggest combining, in a dry mixture, certain microorganisms with tetracycline, a well-known *bacteriostatic drug* having no effect on a dry, quiescent microorganism. Therefore, no one skilled in the art would be motivated to "use ampicillin instead of tetracycline" as suggested by the Examiner.

There must be some suggestion or motivation, either in the references themselves, or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine the reference teachings. *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). Here, there is no suggestion or motivation to combine the reference teachings.

In addition, the prior art must provide a reasonable expectation of success for the proposed modification. *In re Dow Chemical Co. v. American Cyanamid Co.*, 837 F.2d 469 (Fed. Cir. 1988). As the Examiner admits, the field of biotechnology is so unpredictable. As such, no one would necessarily know that combining the teachings of the cited references would be successful.

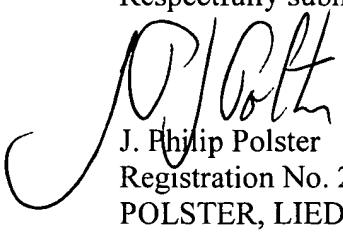
In sum, the Examiner has not established a *prima facie* case for obviousness of independent amended claims 1 and 15. Therefore, Applicant requests withdrawal of the rejection of amended claims 1 and 15 under 35 U.S.C. § 103(b).

Newly presented independent claims 25, 36, and 38 are believed to be allowable over the cited art for the same reasons given above. In addition, claim 38, being limited to formulations "wherein the anti-infective agent would destroy the viability of the microorganism in the dry formulation in less than three months in the absence of the protective barrier" is believed to emphasize the reasons that combining the references would not have been obvious to those skilled in the art at the time the invention was made.

The dependent claims are believed to be patentable for the same reasons as the independent claims. Moreover, they add limitations which, in the claimed combinations, would not have been obvious to those skilled in the art. Therefore, it is respectfully requested that the rejection of the claims under 35 U.S.C. §103(b) be withdrawn.

Should the Examiner not be prepared to allow all of the claims, he is again requested to call Applicants' undersigned attorney to arrange an interview.

Respectfully submitted,



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